

### **REMARKS**

Pending claims 1, 3, 26-27, 33-34, 36, 38, 42-45, and 66-77 presently stand rejected. Claims 2, 4-18, 20-25, 28-32, 41, 46-54, 56, and 62-65 were indicated in the Office Action Summary as being withdrawn from consideration. However, claims 21-25 were canceled with Applicants' Amendment and Interview Summary Record filed on August 28, 2006. Applicants respectfully request that the Patent Office's records be corrected to reflect that claims 21-25 are no longer pending. Claims 19, 35, 37, 55, and 57-61 have also been canceled as reflected in the Office Action Summary. Claims 39-40 are pending and stand as being merely objected to.

Claims 1, 38, 40-41, 66, 69, and 75 are amended herewith. Claim 39 has been canceled. Claims 78-79 have been added. Thus, upon entry of this amendment and accompanying remarks, claims 1-18, 20, 26-34, 36, 38, 40-54, 56, and 62-79 are pending in the present application, with claims 2, 4-18, 20, 28-32, 41, 46-54, 56, and 62-65 being withdrawn in the absence of rejoinder as requested herein.

#### **The 35 U.S.C. §102(b) Rejection**

Claims 1, 3, 26-27, 33-34, 36, 38, and 42-45 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by European Patent Document No. EP 0 346 957 ("Bristow") as evidenced by Poisoning & Drug Overdoses (2004). This rejection is respectfully traversed. Withdrawal thereof is requested.

On page 2, last paragraph, of the Office Action, the Examiner states: "Claim 1 is directed toward a composition comprising 0.5-10% aqueous soluble divalent strontium cation and a suitable topical vehicle." However, Applicants note that pending claim 1, without the current amendment introduced in this Response, recites a composition comprising: "a salt comprising aqueous-soluble divalent strontium cation in an amount of about 0.5% by weight to about 14% by weight of the total formulation, an irritant ingredient, and a suitable topical formulation vehicle." (emphasis added) Claims 3, 26-27, 33-34, 36, 38, and 42-45 ultimately depend from claim 1.

As a preliminary matter, Applicants note that claim 1 is amended herewith to incorporate claim 39 therein (which claim was indicated to be allowable if rewritten in

independent form and is, thus, hereby canceled due to the amendment of claim 1). Claims 3, 26-27, 33-34, 36, 38, and 42-45 depend, directly or indirectly, from claim 1. As such, it is believed that, by incorporation of claim 39 into claim 1, the present rejection is overcome in its entirety as Bristow does not teach or suggest each and every element of amended claim 1 as acknowledged by the Examiner (in merely objecting to claim 39) in the Office Action. Further analysis and discussion of the substance of this rejection is hence unnecessary and is not included at this time.

#### The 35 U.S.C. §102(e) Rejection

Claims 1, 3, 66-70, and 75-77 stand rejected under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent No. 5,470,563 ("Tanaka"). This rejection is respectfully traversed.

On page 4, second paragraph, of the Office Action the Examiner refers to Example 5-5 of Tanaka in asserting that claims 1, 3, 66-70 and 75-77 are anticipated thereby.<sup>1</sup> On page 4, first paragraph, of the Office Action the Examiner also refers to Example 5-1 of Tanaka in asserting that claims 66 and 68-69 are anticipated thereby.

As a preliminary matter, Applicants again note that claim 1 is amended herewith to incorporate claim 39 therein (which claim was indicated to be allowable if rewritten in independent form). Claims 3 and 76-77 ultimately depend from claim 1. As such, it is believed that, by incorporation of claim 39 into claim 1, the present rejection is overcome as applied to claims 1, 3, and 76-77 as Tanaka does not teach or suggest each and every element of amended claim 1 as acknowledged by the Examiner (in merely objecting to claim 39) in the Office Action. Further analysis and discussion of the substance of this rejection as applied to claims 1, 3, and 76-77 is hence unnecessary and is not included at this time. Withdrawal of this rejection with respect to claims 1, 3, and 76-77 is respectfully requested.

Claim 66, as currently amended, recites a topical formulation for reducing skin irritation comprising "a non-strontium active ingredient for effecting primary activity of

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<sup>1</sup> The Office Action referenced "Example 5-," which is presumed to be Example 5-5 based on the reference to 6% strontium hydroxide in the Office Action and the inclusion of that component in Example 5-5 of Tanaka.

the topical formulation; a skin irritation reducing salt comprising aqueous-soluble divalent strontium cation; and a suitable topical formulation vehicle, with the proviso that the topical formulation is not a dentifrice.” Support for this amendment can be found throughout the originally filed specification, including the title of the patent application. Claims 67-68 depend from claim 66.

As a preliminary matter, the language of claim 66 is addressed in view of the Office Action. The Examiner indicates on page 3, first paragraph, of the Office Action that the phrases “for effecting primary activity of the topical formulation” and “with the proviso that the topical formulation is not a dentifrice” were given no patentable weight on the presumption that such phrases merely denoted intended uses of the composition.<sup>2</sup> Applicants respectfully disagree with the Examiner’s characterization of these phrases, both of which are contained within the body of the claim.

The referenced phrases define the composition, not the use, of the claimed formulations. For example, formulations other than those recited in claim 66 may contain a non-strontium active ingredient (*e.g.*, an anesthetic or other active ingredient as recited in originally filed claim 20 of the present application), which is not an active ingredient for effecting primary activity (*e.g.*, depilatory or other activity) of the topical formulation. The latter active ingredient would be, for example, a depilatory agent when the formulation is a depilatory formulation. In that case, the former non-strontium active ingredient is not “a non-strontium active ingredient for effecting primary activity of the topical formulation.” Simply stated, compositions of claim 66 are defined, in part, by their primary function.

Likewise, “the proviso that the topical formulation is not a dentifrice” defines the composition recited in claim 66. A composition that is void of ingredients necessary for cleaning and/or polishing teeth is outside the scope of the term “dentifrice.” In contrast, if a formulation contains such teeth cleaning and/or polishing agents, one of ordinary skill in the art would understand that such a formulation is generally referred to as a dentifrice.

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<sup>2</sup> Although the Examiner’s referenced statement was made with respect to claim 65 and the rejection of claims 1, 3, 26-27, 33-34, 36, 38, and 42-45 under 35 U.S.C. §102(b), it is believed that this was an inadvertent error and that the statement was intended to be made with respect to claim 66 and its rejection under 35 U.S.C. §102(e).

Thus, both phrases referenced by the Examiner on page 3, first paragraph, of the Office Action are not merely intended uses, but rather such phrases assist in defining the formulation recited in claim 66. In any event, Tanaka does not teach or suggest each and every element of claim 66. For example, Tanaka does not teach or suggest a topical formulation for reducing skin irritation comprising a non-strontium active ingredient for effecting primary activity of the topical formulation.

As acknowledged by the Examiner on page 4 of the Office Action, strontium sulfide serves as a depilatory agent in the formulation of Example 5-1 – a “depilatory” – as referenced by the Examiner in setting forth this rejection. Thus, the active ingredient for effecting primary activity of the topical formulation of Example 5-1 is strontium sulfide, which obviously contains strontium and is not a non-strontium active ingredient as recited in claim 66. Further, Example 5-1 does not teach or suggest a formulation comprising a skin irritation reducing salt comprising aqueous-soluble divalent strontium cation. Rather, Example 5-1 teaches the inclusion of polyoxyalkylene-modified organopolysiloxane for reducing skin irritation otherwise resulting when using the formulation. Therefore, each and every element of claim 66 is not taught or suggested thereby.

In rejecting claim 66, the Examiner also references the “depilatory lotion” set forth as Example 5-5 of Tanaka, which depilatory lotion contains 7% calcium thioglycolate and 6% strontium hydroxide. In this case, the combination of strontium hydroxide, an alkalizing agent, and calcium thioglycolate, the depilatory agent, effects depilatory action. Based on knowledge of those of ordinary skill in the art, strontium hydroxide would not be expected to reduce skin irritation, but its presence would be necessary in conjunction with the depilatory agent to achieve the desired depilatory effect. Further, its presence would be expected to increase skin irritation. For example, see col. 2, lines 50-63, of U.S. Patent No. 3,981,681, which states:

The pH of the depilatory composition should be adjusted to a value of about 11.5 - about 12.7 . . . . Generally, alkalizing agents will be used to adjust the pH, with calcium hydroxide, for instance, being a suitable alkalizing agent due to the reduced irritation encountered therewith. Other alkalizing agents which could be used include sodium hydroxide, lithium hydroxide, strontium hydroxide, and the like, but it should be understood that substantially greater irritation may be

encountered with such products and for that reason they are generally avoided.  
(emphasis added)

Indeed, the stated alleviator of skin irritation in Tanaka - polyoxyalkylene-modified organopolysiloxane - is contained in the composition of Example 5-5 to reduce skin irritation otherwise resulting when using the formulation. Thus, Applicants respectfully submit that Example 5-5 also does not teach or suggest each and every element of claim 66. Thus, withdrawal of this rejection with respect to claim 66, as well as claims 67-68 due to their dependency from claim 66, is respectfully requested.

Further with respect to dependent claim 68, Applicants note that claim 68 recites: "The formulation of claim 66, wherein salt in the formulation consists essentially of aqueous-soluble divalent strontium cation and one or more counteranions." Tanaka does not teach or suggest each and every element of claim 68. In the case of Tanaka's Example 5-5, for example, strontium hydroxide is not the only salt in the composition. In fact, the most prevalent component in the depilatory lotion of Example 5-5 is calcium thioglycolate in the amount of 7%. As calcium thioglycolate is also a salt, Example 5-5 is not capable of supporting the present rejection of claim 68. Withdrawal of the present rejection as applied to claim 68 is respectfully requested for this further reason.

Claim 69, as currently amended, recites a "depilatory formulation comprising: a depilatory agent; and a skin irritation reducing salt comprising aqueous-soluble divalent strontium cation." Support for this amendment can be found throughout the originally filed specification, including the title of the patent application. Claim 70 depends from claim 69 and specifies that the "depilatory agent is non-strontium."

Tanaka does not teach or suggest each and every element of claim 69. As discussed above and as acknowledged by the Examiner on page 4 of the Office Action, strontium sulfide serves as a depilatory agent in the formulation of Example 5-1. No other strontium-containing component is included within Tanaka's Example 5-1. Again claim 69 recites a depilatory formulation comprising both a depilatory agent and a salt comprising aqueous-soluble divalent strontium cation. Further, Example 5-1 does not teach or suggest a formulation comprising a skin irritation reducing salt comprising aqueous-soluble divalent strontium cation as recited in amended claim 69. Rather,

Example 5-1 teaches the inclusion of polyoxyalkylene-modified organopolysiloxane for reducing skin irritation otherwise resulting when using the formulation. Therefore, Tanaka's Example 5-1 does not support the present rejection of claim 69 as each and every element of claim 69 is not taught or suggested thereby.

In rejecting claim 69, the Examiner also references Example 5-5 of Tanaka, which describes a depilatory lotion containing 7% calcium thioglycolate and 6% strontium hydroxide. In this case, the combination of strontium hydroxide, an alkalizing agent, and calcium thioglycolate, the depilatory agent, effects depilatory action. As discussed above, based on knowledge of those of ordinary skill in the art, strontium hydroxide would not be expected to reduce skin irritation, but its presence would be necessary in conjunction with the depilatory agent to achieve the desired depilatory effect. Further, its presence would be expected to increase skin irritation. For example, see col. 2, lines 50-63, of U.S. Patent No. 3,981,681. Indeed, the stated alleviator of skin irritation in Tanaka - polyoxyalkylene-modified organopolysiloxane - is contained in the composition of Example 5-5 to reduce skin irritation otherwise resulting when using the formulation. Thus, Applicants respectfully submit that Tanaka's Example 5-5 also does not teach or suggest each and every element of claim 69. Thus, withdrawal of this rejection with respect to claim 69, as well as claim 70 due to its dependency from claim 69, is respectfully requested.

Claim 75, as currently amended, recites a composition "for effective removal of hair with reduced skin irritation, the composition comprising: a non-strontium active agent for removal of hair; and a skin irritation reducing salt comprising aqueous-soluble strontium cation." Support for this amendment can be found throughout the originally filed specification, including the title of the patent application.

The Examiner indicates on page 4, third paragraph, of the Office Action that the phrase "for effective removal of hair with reduced skin irritation" was given no patentable weight on the presumption that such phrase merely denotes an intended use or purpose of the composition. Similar to the reasoning discussed above with respect to the language of claim 66, Applicants respectfully submit that the referenced phrase defines the composition, not merely its use.

Nevertheless, Tanaka does not teach or suggest each and every element of claim 75. For example, as discussed above and as acknowledged by the Examiner on page 4 of the Office Action, strontium sulfide serves as a depilatory agent (*i.e.*, an active agent for removal of hair) in the formulation of Example 5-1. No other strontium-containing component is included within Tanaka's Example 5-1. Again claim 75 recites a depilatory formulation comprising both a non-strontium active agent for removal of hair and a salt comprising aqueous-soluble divalent strontium cation. Further, Example 5-1 does not teach or suggest a formulation comprising a skin irritation reducing salt comprising aqueous-soluble divalent strontium cation as recited in amended claim 75. Rather, Example 5-1 teaches the inclusion of polyoxyalkylene-modified organopolysiloxane for reducing skin irritation otherwise resulting when using the formulation. Therefore, Tanaka's Example 5-1 does not support the present rejection of claim 75 as each and every element of claim 75 is not taught or suggested thereby.

In rejecting claim 75, the Examiner references Example 5-5 of Tanaka, which describes a depilatory lotion containing 7% calcium thioglycolate and 6% strontium hydroxide. In this case, the combination of strontium hydroxide, an alkalizing agent, and calcium thioglycolate, the depilatory agent, effects depilatory action. As discussed above, based on knowledge of those of ordinary skill in the art, strontium hydroxide would not be expected to reduce skin irritation, but its presence would be necessary in conjunction with the depilatory agent to achieve the desired depilatory effect. Further, its presence would be expected to increase skin irritation. For example, see col. 2, lines 50-63, of U.S. Patent No. 3,981,681. Indeed, the stated alleviator of skin irritation in Tanaka - polyoxyalkylene-modified organopolysiloxane - is contained in the composition of Example 5-5 to reduce skin irritation otherwise resulting when using the formulation.

Thus, withdrawal of this rejection with respect to claim 75 is respectfully requested as each and every element thereof is not taught or suggested by Tanaka. Further, as Tanaka does not teach or suggest each and every element of any of the rejected claims, withdrawal of this rejection in its entirety is respectfully requested.

The 35 U.S.C. §103 Rejection

Claims 71-74 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 5,470,563 (“Tanaka”) as applied to claims 1, 3, 66, 68, and 75-77, and further in view of European Patent Document No. EP 0 346 957 (“Bristow”). This rejection is respectfully traversed.

Claims 71-74 depend, directly or indirectly, from independent claim 69. As discussed above with respect to the rejection of claim 69 based on Tanaka under 35 U.S.C. §102(e), each and every element of claim 69 is not taught or suggested by Tanaka. The asserted combination of Tanaka with Bristow does not overcome the deficiencies of Tanaka. Further, Applicants respectfully submit that the Examiner has not established a prima facie case of obviousness in rejecting any of claims 71-74 based on Tanaka in view of Bristow.

Claim 71 recites a depilatory formulation comprising a depilatory agent and a salt comprising aqueous-soluble divalent strontium cation “wherein the salt comprises one or more acidic anion species.” On page 4, last paragraph, of the Office Action the Examiner asserts that modifying Tanaka to teach acidic anion species “is well within the skill of the art, absent evidence of unexpected results.” The Examiner then continues on page 5 to assert that it would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the strontium salts of Tanaka by substituting the salts with other water-soluble strontium compounds as motivated by Bristow since both references are directed to the use of strontium salts in pharmaceutical compositions and Bristow teaches pharmaceutically acceptable salt form of strontium.” Applicants respectfully disagree.

A prima facie case of obviousness has not been established. As set forth in the Manual of Patent Examining Procedure (MPEP) §2143:

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.



The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Notably absent is a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the teachings of Bristow and Tanaka as suggested in the Office Action. Even if that were the case, especially given the different environments in which the compositions of Bristow and Tanaka are used, no evidence has been presented establishing that a reasonable expectation of successfully combining the teachings exists.

Tanaka is directed toward compositions specifically for “a skin external application composition or a cosmetic or similar composition containing a polyoxyalkylene-modified organopolysiloxane” as discussed throughout. The compositions of Tanaka are used in conjunction with specific cosmetic applications for external skin application – alleviating skin irritation resulting from applying tacky tapes to the external skin. In contrast, Bristow is specifically related to “oral compositions.” Obviously, markedly different considerations apply when formulating compositions for internal, as opposed to external, applications and there is no motivation or suggestion within the cited art to combine the disparate teachings of Bristow and Tanaka in that regard. Further, there is no evidence within the cited art that such a combination would reasonably be expected to succeed. As the Examiner has not met the burden of establishing a prima facie case of obviousness in setting forth the rejection, this rejection cannot be sustained. Withdrawal thereof is respectfully requested.

In addition, reference is made to the last paragraph on page 4 of the Office Action, where the Examiner states: “While Takana fails to teach acidic anion species, examiner takes the position that varying different mineral acids to produce strontium salts is well within the skill of the art, absent evidence of unexpected results.” Applicants submit that the invention recited in claims 71-74 is not trivial. In that regard, Applicants draw the Examiner’s attention to Paragraph 0036 of the publication of the present application (U.S. Patent Publication No. 20030031727). Therein, Applicants discuss their discovery that preferred formulations of the invention include “preferably an acidic

anion species such as a chloride, nitrate, or acetate anion.” As further discussed in Paragraph 0062-0063 therein:

Clinical trials relating to the invention have established that certain cation-anion pairs are particularly active as anti-irritants. These include strontium chloride, strontium nitrate, and strontium acetate.

Also preferred are these and other cation-anion pairs in which the anionic species is acidic, because such pairs will generally exhibit higher solubility in many common topical vehicles and suitable ionization upon application to the skin. In addition, strongly acidic anion components may be useful where it is desired to maintain the pH of the resulting formulation at a relatively acidic level, as for example in the case of hydroxy-acid or other acidic exfoliant products where the activity of the product to exfoliate or reduce wrinkles, or bring about other beneficial effects may be reduced if the formulation is not relatively acidic. In any event, however, the desired level of acidity in such cases can be achieved by adjusting the formulation with a suitable acid (or base if necessary).

For the foregoing reasons, withdrawal of this rejection is respectfully requested.

#### The Double Patenting Rejections

##### *The First Rejection*

Claims 1, 3, 38-40, and 66-68 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-21, 34, 43, and 54 of U.S. Patent No. 5,716,625.

Applicants note that the term of any patent issuing from the present application, absent any patent term adjustment or other terminal disclaimers, is the same as that of U.S. Patent No. 5,716,625. Thus, a terminal disclaimer is being filed herewith to obviate the present double patenting rejection based on U.S. Patent No. 5,716,625. Withdrawal of this rejection is, therefore, respectfully requested.

*The Second Rejection*

Claims 1, 3, 26-27, 33-34, 38-40, and 66-68 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-3, 21-22, 24-26, 31-33, 35-40, 60-61, 70, and 81 of U.S. Patent No. 5,804,203.

Applicants note that the term of any patent issuing from the present application, absent any patent term adjustment or other terminal disclaimers, is the same as that of U.S. Patent No. 5,804,203. Thus, a terminal disclaimer is being filed herewith to obviate the present double patenting rejection based on U.S. Patent No. 5,804,203. Withdrawal of this rejection is, therefore, respectfully requested.

*The Third Rejection*

Claims 1, 3, 38-40, and 66-68 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-2, 10-22, 33, 43, 70-75, and 82 of U.S. Patent No. 5,958,436.

Applicants note that the term of any patent issuing from the present application, absent any patent term adjustment or other terminal disclaimers, is the same as that of U.S. Patent No. 5,958,436. Thus, a terminal disclaimer is being filed herewith to obviate the present double patenting rejection based on U.S. Patent No. 5,958,436. Withdrawal of this rejection is, therefore, respectfully requested.

*The Fourth Rejection*

Claims 1, 3, 38-40, and 66-68 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1, 10-22, 30, 41, 44, 60, 83, and 97-98 of U.S. Patent No. 6,139,850.

Applicants note that the term of any patent issuing from the present application, absent any patent term adjustment or other terminal disclaimers, is the same as that of U.S. Patent No. 6,139,850. Thus, a terminal disclaimer is being filed herewith to obviate the present double patenting rejection based on U.S. Patent No. 6,139,850. Withdrawal of this rejection is, therefore, respectfully requested.

#### New Claims

Claim 78 is hereby added as a subset of originally filed claims 33 and 34 in independent form. Claims 33 and 34 were rejected in the Office Action only under 35 U.S.C. §102(b) as allegedly being anticipated by European Patent Document No. EP 0 346 957 (“Bristow”) as evidenced by Poisoning & Drug Overdoses (2004). However, the Office Action contains no specific discussion of each of the elements of these two claims now recited in claim 78 vis-à-vis the cited documents. As Bristow is directed solely toward oral compositions for treating sensitive teeth, it is respectfully submitted that each and every element of new claim 78 is not taught or suggested thereby. Indeed, Bristow does not teach or suggest compositions containing formulation vehicles comprising at least one ingredient selected from the group consisting of emollients, moisturizers, fragrances, dyes, and pigments, nor is this surprising given the intended oral use (for treating sensitive teeth) of compositions therein. As such, allowance of new claim 78 is hereby respectfully requested.

Claim 79 is hereby added as a subset of previously presented claim 38 in independent form. Claim 38 was rejected in the Office Action only under 35 U.S.C. §102(b) as allegedly being anticipated by European Patent Document No. EP 0 346 957 (“Bristow”) as evidenced by Poisoning & Drug Overdoses (2004). However, the Office Action contains no specific discussion of the elements of claim 38 vis-à-vis the cited documents. As Bristow is directed solely toward oral compositions for treating sensitive teeth, it is respectfully submitted that each and every element of new claim 79 is not taught or suggested thereby. Indeed, Bristow does not teach or suggest compositions containing an active ingredient selected from the group of local anesthetic, sunscreen, retinoid, antiperspirant, antihistamine, analgesic, contraceptive, anti-acne and anti-

dandruff ingredients, nor is this surprising given the intended oral use (for treating sensitive teeth) of compositions therein. As such, allowance of new claim 79 is hereby respectfully requested.

Conclusion

In view of the foregoing, allowance of all pending claims is respectfully requested. Further, due to their ultimate dependency from pending claim 1, rejoinder and allowance of all withdrawn claims is also requested. If deemed useful in order to further prosecution of this application to allowance, the Examiner is invited to contact the undersigned by telephone, e-mail, facsimile, or written communication.

Respectfully Submitted,

Date: 2-28-07

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